SMG 1410.423

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – Medical Devices and Radiological Health

Unique Device Identifier

Effective Date: 15 November 2021

1. Authority Delegated and To Whom Delegated.

A. The officials listed below are authorized to perform the functions of the Commissioner of Food and Drugs under section 519(f) of the Federal Food, Drug & Cosmetic Act (FD&C Act) (21 U.S.C. 360i(f)), and under 21 CFR 801.55 as regards to granting or rescinding an exception from or alternative to, either in response to a request or on their own initiative, a requirement related to a unique device identifier:

(1) Center for Biologics Evaluation and Research (CBER) Director, Deputy Directors, Associate Director for Review Management, and Deputy Associate Director for Review Management.

(2) Center for Devices and Radiological Health (CDRH) Director, Deputy Center Director for Policy, and Deputy Center Director for Science.

(3) CDRH/Office of Product Evaluation and Quality (OPEQ) Director, Principal Deputy Director, Deputy Director for Operations, and Deputy Director for Regulatory Policy.

(4) CDRH/OPEQ/Office of Regulatory Programs (ORP) Director.

(5) CDRH/Office of Strategic Partnerships and Technology Innovation (OSPTI) Director and Deputy Director.

(6) CDRH/OSPTI/Division of Technology and Data Services (DTDS) Director and Deputy Director.

B. The officials listed below are authorized to grant, renew, suspend or revoke the accreditation of an issuing agency under 21 CFR 830 Subpart C:

(1) CBER Director, Deputy Directors, Associate Director for Review Management, and Deputy Associate Director for Review Management.

(2) CDRH Director, Deputy Center Director for Policy, and Deputy Center Director for Science.

(3) CDRH/OPEQ Director, Principal Deputy Director, Deputy Director for Operations, and Deputy Director for Regulatory Policy.

(4) CDRH/OPEQ/ORP Director.

(5) CDRH/OSPTI Director and Deputy Director.

(6) CDRH/OSPTI/DTDS Director and Deputy Director.

C. The officials listed below are authorized to determine that FDA will act as an issuing agency as set forth in 21 CFR 830.200 and to terminate FDA's services as an issuing agency under 21 CFR 830.220:

(1) CBER Director, Deputy Directors, Associate Director for Review Management, and Deputy Associate Director for Review Management.

(2) CDRH Director, Deputy Center Director for Policy, and Deputy Center Director for Science.

(3) CDRH/OPEQ Director, Principal Deputy Director, Deputy Director for Operations, and Deputy Director for Regulatory Policy.

(4) CDRH/OPEQ/ORP Director.

(5) CDRH/OSPTI Director and Deputy Director.

(6) CDRH/OSPTI/DTDS Director and Deputy Director.

2. Redelegation.

These officials may not redelegate these authorities.

3. Effective Date.

The Acting Commissioner of Food and Drugs approved this delegation, via memorandum, on 15 November 2021.

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	11/15/2021	N/A	CDRH/ OP	Janet Woodcock, M.D. Acting Commissioner of Food and Drugs